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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/301,906 04/29/99 GONSALVES D 07678/07/002

HM22/0829

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EXAMINER

COLLINS, C

ART UNIT

PAPER NUMBER

1638

15

DATE MAILED:

08/29/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/301,906	Applicant(s) GONSALVES ET AL.	
	Examiner Cynthia Collins	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 10, 12 and 16-34 is/are pending in the application.
- 4a) Of the above claim(s) 1-5, 7, 10, 14, 16-18 and 32-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6, 12 and 19-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>12</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group VII, claims 6, 12, and 19-31, in Paper No. 14 is acknowledged. The traversal is on the ground(s) that the restriction requirement is inconsistent with the provisions of the partial waiver of 37 C.F.R. § 1.141 for nucleotide sequences and is contradictory with respect to MPEP § 803.04. This is not found persuasive because 37 C.F.R. § 1.141 and MPEP § 803.04 permit but do not require the examiner to waive restriction to no more than one independent and distinct nucleotide sequence. Since 1996, databases and resource allocations at the PTO have changed, and the examination of up to 10 independent and distinct nucleotide sequences would present a burden on PTO resources.
2. Applicant's request for reconsideration and modification of the restriction requirement has been fully considered, but is not persuasive.
3. Applicant's request to combine Examiner's Groups VII-XIV into Applicant's Group I, and Applicant's request to combine Examiner's Groups XXV-XXXI into Applicant's Group II, is not persuasive because of the search burden imposed for searching more than one independent and distinct nucleotide sequence. Applicant's request to combine Examiner's Groups XV-XIX into Applicant's Group III, and Applicant's request to combine Examiner's Groups XX-XXIV into Applicant's Group IV, is not persuasive because of the search burden imposed for searching more than one independent and distinct antibody. Applicant's request to combine Examiner's Groups I-VI into Applicant's Group V is not persuasive because of the search burden imposed for searching more than one independent and distinct polypeptide sequence.
4. Claims 1-5, 7, 10, 14, 16-18, and 32-34 are withdrawn as being directed to nonelected inventions.

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5. The requirement is still deemed proper and is therefore made FINAL.

Priority

6. A foreign priority is not claimed.

Information Disclosure Statement

7. Initialed and dated copies of Applicant's IDS forms 1449, Paper Nos. 4,6,10, and 12, are attached to the instant Office action.

Drawings

8. The drawings are objected to by the Draftsperson as informal for the reasons indicated on Form PTO 948.

Claim Objections

9. Claim 6 is objected to because it depends on a claim that was withdrawn as being directed to a nonelected invention (claim 1). Appropriate correction is required.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 6, 12, and 19-31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
2. The claims are drawn to an isolated RNA molecule encoding a grapevine leafroll virus protein comprising a proteinase, an isolated DNA molecule that encodes a proteinase and that hybridizes under highly stringent conditions to the complement of SEQ ID NO:4, an expression

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vector, a host cell, a transgenic plant, and a method of conferring viral disease resistance to a plant or component.

3. However, the specification does not set forth any specific structural or physical characteristics of the claimed isolated nucleic acids that define their function, such as the identification of specific nucleotides whose alteration affects the proteinase function of the protein they encode. The specification only discloses that ORF1a (SEQ ID NO:4) has homology to a known viral proteinase (pages 20-22 *Example 1*, page 6 lines 11-12, page 7 lines 23-28). The identities of the claimed isolated nucleic acids and expression vectors, host cells, and transgenic plants are uncertain. One skilled in the art could not predict what the structure and function of the claimed isolated nucleic acids and expression vectors, host cells, and transgenic plants would be. The physical features of the claimed isolated nucleic acids and expression vectors, host cells, and transgenic plants cannot be ascertained in the absence of information about their functional activities.

4. See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997), where it states:

"The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA ... Accordingly, the specification does not provide a written description of the invention ..."

5. Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed isolated nucleic acids and expression vectors, host cells, and transgenic plants, and given the high level of unpredictability in this art of determining the function of an isolated nucleic acid on the basis of homology, one skilled in the

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art would not have been in possession of the claimed isolated nucleic acids and expression vectors, host cells, and transgenic plants at the time this application was filed.

6. Claims 6, 12, and 19-31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

7. The claims are drawn to an isolated RNA molecule encoding a grapevine leafroll virus protein comprising a proteinase, an isolated DNA molecule that encodes a proteinase and that hybridizes under highly stringent conditions to the complement of SEQ ID NO:4, an expression vector, a host cell, a transgenic plant, and a method of conferring viral disease resistance to a plant or component.

8. In the instant disclosure, applicants teach only the cloning of the grapevine leafroll virus genome of GLRaV-3, and the identification of ORFs within that genome, including an ORF (ORF1a, SEQ ID NO:4) that has homology to a known viral proteinase (pages 20-22 *Example 1*, page 6 lines 11-12, page 7 lines 23-28).

9. However, the specification does not provide any definitive evidence that SEQ ID NO:4, or any sequence that hybridizes to SEQ ID NO:4, encodes a functional proteinase, such as demonstrating proteinase activity in vitro using a recombinant protein encoded by SEQ ID NO:4. In addition, the specification does not teach any examples of how to make or use expression vectors, host cells, or transgenic plants comprising the claimed isolated nucleic acids. Finally, the specification does not disclose whether transforming a plant cell with the claimed isolated nucleic acids would confer viral disease resistance to a transformed plant or component.

10. Guidance for making and using the claimed invention is necessary for enablement because the ability of a particular viral transgene to confer viral disease resistance in a transgenic plant is highly unpredictable.

11. Vardi et al. teach transgenic tobacco plants transformed with a potato virus Y (PVY) protease gene (August 1993, Proc. Natl. Acad. Sci. USA, Vol. 90, pages 7513-7517). Forty-eight of fifty transgenic lines analyzed were susceptible to viral infection (page 7514 column 2 second full paragraph). In addition, two PVY susceptible R2 transgenic lines expressed as well as carried the protease transgene (page 7515 column 1 first paragraph). Only forty to fifty percent of the R1 plants of the two PVY resistant lines, V2 and V3, remained symptomless 50 days after PVY inoculation (page 7515 *Table 2*).

12. Guidance for making and using the claimed invention is also necessary for enablement because the spectrum of disease resistance conferred by a particular viral transgene can vary depending on the nature of the transgene.

13. Maiti et al. teach transgenic tobacco plants transformed with a tobacco vein mottling virus (TVMV) proteinase gene (July 1993, Proc. Natl. Acad. Sci. USA, Vol. 90, pages 6110-6114). Transgenic plants that were resistant to the TVMV potyvirus were not resistant to two other potyviruses (page 6112 *Table 1*). Maiti et al. contrast this observation with the broad-spectrum of resistance known to be conferred by potyvirus coat protein transgenes (page 6110 column 2 lines 1-5).

14. Because the ability of the claimed isolated nucleic acids to confer viral disease resistance to a plant has not been demonstrated, the claimed invention is not enabled by the specification in the absence of further guidance or example.

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15. Given the unpredictability of conferring viral disease resistance to a plant using isolated nucleic acids encoding viral proteinases, the absence of guidance in the specification for making and using transgenic host cells and plants comprising said isolated nucleic acids, the lack of working examples, and given the breadth of the claims which encompass isolated nucleic acid sequences having sequence homology to SEQ ID NO:4 as well as transgenic host cells and plants comprising said isolated nucleic acid sequences, it would require undue experimentation by one skilled in the art to make and/or use the claimed invention.

Remarks

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell can be reached on (703) 308-4310. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and 1 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
August 23, 2001

ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1800
E. F. McElwain